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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,573	04/19/2000	Gary K. Michelson M.D.	101.0077-00000	3776

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MARTIN & FERRARO, LLP
1557 LAKE O'PINES STREET, NE
HARTVILLE, OH 44632

EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/553,573	MICHELSON M.D., GARY K.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-34,36-38,40-42,101-130,132-135 and 137-174* is/are pending in the application.

4a) Of the above claim(s) 3 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,11-34,36-38,40-42,101-130,132-135 and 137-174* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/19/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed 1/19/07 have been fully considered.

Rejected under 35 U.S.C. 102(b) as being anticipated by Cottle (5,888,227).

Applicant's amendment describing the leading end having a curved portion which extends to at least the mid-longitudinal axis overcame the rejection.

Rejection under 35 U.S.C. 103(a) as being unpatentable over Williams et al.

Applicant argues that Williams fails to teach the leading end including a curved portion the extends from the exterior wall to at least the mid-longitudinal axis of the implant; this is not persuasive. Referring to at least figure 2 of Williams the leading end is interpreted as either the anterior end or posterior end which meets the claim limitation. It is noted that "leading end" is merely a functional description in which either the anterior or posterior end of Williams et al fulfills. See all embodiments including figures 5B and 5D having the leading end which contains hole 107.

Rejection under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Brantigan (5,192,327).

Applicant argues that the Michelson reference already taught the modification of a spinal implant formed in two halve device and cannot be modified. The Examiner strongly disagrees. Michelson does not teach the implants 18-23 are hemi-devices as stated in column 10, lines 9-16, but only that they are sized to be placed next to each other. Michelson failed to teach the implant like those of figures 1-17 can be formed in half or being less than approximately one-half the maximum width of the adjacent

vertebrae. The Brantigan reference clearly states the advantages of forming a "hemi" device. Michelson contemplates the implants being smaller wherein it takes four to fill the intervertebral space; see 10:9-16. Michelson also fails to teach maintaining a shape similar to the vertebrae shape when forming these smaller implants.

Again the term "leading end" is merely a functional description. The hemi devices of Michelson in view of Brantigan are capable of being inserted in varying directions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

All claims are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all claims of U.S. Patent No. 6,666,890 and all claims of 7,022,137. Although the conflicting claims are not identical, they are not

patentably distinct from each other because they claim the same implant comprising the same limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-8,11-34, 36-38,40-42, 101-130, 132-135, 137-174 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams et al (6,113,638).

Referring to figure 2, Williams et al teaches an artificial interbody spinal implant comprising a leading end (interpreted as either anterior or posterior ends) for insertion first into the disc space, the leading end being asymmetrical from side to side; and

opposed portions (top and bottom) being non-actuate along a portion of the length.

It is the Examiner's position that it is within the scope of the teachings of Williams et al that making a hemi-device applies to all taught embodiments. As shown in figures 1-2, the present invention 10 comprises a first and second anchor plates 12 and 14 and an intradiscal component 16 and teaches the device can be formed into halves as a hemicircle or hemioval. See 5:32-6:4. Williams refers to the device as first and second hemi-device. Now referring to the present invention shown in figure 5A-5D, this configuration also uses first and second anchor plate and an intradiscal component; dividing this configuration into a hemi-device takes no special engineering and a hemi-device of figures 5 would produce an implant with an exterior sidewall which is in part linear along the length.

Referring to at least figure 5A, the opposed portions have at least one opening 103 or 104 and 101/115. At least openings 101/115 having a dimension less than the maximum dimension between the interior and exterior facing side walls when the device is formed as a hemi-device. Also see figure 7A.

Regarding the implant materials, see at least 7:8 et seq., which includes BMP.

Regarding the first distance greater than the second distance, etc., referring to at least figures 2 and 5D and wherein the device is formed as a hemi-device, the leading end can be interpreted as either the end containing opening 107 or the opposite end. Either end fulfills the claim limitation. It is noted "leading end" is a functional description in which either end of the device of Williams can function as.

In the alternative, under 35 U.S.C. 103(a) as obvious over Williams et al:

Williams teaches the present invention with the configurations as shown in at least figures 5A-5D, however, applicant has suggested that it is unclear as to forming at least these configurations into hemi-devices. Williams in figures 1-2 teach forming the present invention into hemi-devices. It would have been obvious to one having ordinary skill in the art to have used the teaching of Williams to form at least the configurations of the present invention shown in figures 5A-5D of Williams into hemi-devices because, "*hemioval implantable devices [30] and [32] can be used to approximate the intradiscal space and conform with the general outline perimeter of the vertebrae. Such an implantable device with a hemioval size allows better access to the posterior portion of the spine when the devices are implanted through a posterior approach. For example, the first hemi-device 30 can be inserted into and fill in half of*

the intradiscal space without colliding with the spinal cord 15, then followed by placing the second hemi-implantable device 32 to fill in the other half of the intradiscal space (5:51 et seq.)".

One skilled in the art in the art would find it inherent or at least obvious would dividing the various embodiments of the present invention into halves to form an interior side wall.

The implants are configured to conform to the anatomic contour of the vertebral bodies, inherently, the leading end of each implant is seated on and corresponds to the contour of at least one of the anterior and posterior portions of the apophyseal rim bone area without at least a portion of the implant proximate the leading end substantially extending beyond the outer dimensions of the vertebral bodies; see figures 1, 2 and 9D.

Regarding independent claims 102 and 147 requiring the exterior wall facing side including a straight portion, note figures 5A and 7A teaching said limitation.

All other limitations are believed self-evident (or well known in the art).

Claims 1, 2, 4-8,11-34, 36-38,40-42, 101-130, 132-135, 137-174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Brantigan (5,192,327).

Referring to figures 1-17, Michelson teaches a spinal implant having an anterior aspect, a posterior aspect, and sidewalls. Michelson further teaches opposed surfaces having at least one opening and said opposed surfaces can be relatively angled. Michelson further teaches all claimed surfaces, elements, and material. Michelson

teaches an implant having a convex leading end interpreted as 130, 230, 330 "which may be curved so as to conform to the shape of the vertebral surfaces" and wherein the "upper and/or lower surfaces may be convex and/or front and/or rear surface" (see column 2, lines 23-34).

However, Michelson fails to teach the implant like those of figures 1-17 are formed in half or being less than approximately one-half the maximum width of the adjacent vertebrae.

Brantigan teaches a similarly configured spinal implant which can be formed in a whole configuration, as shown in figure 1, or in two halves, as shown in figure 2. It would have been obvious to one having ordinary skill in the art to have used the teachings of Brantigan to have formed the spinal implant of Michelson which conforms to the shape of vertebral surface in two *halves "for usage in partial corpectomy operations and also side-by-side relation when an intermediate nerve space is needed (see column 4, lines 57 et seq.)".*

It would have been obvious to one having ordinary skill in the art that in some embodiments, interior walls would be formed for structural integrity.

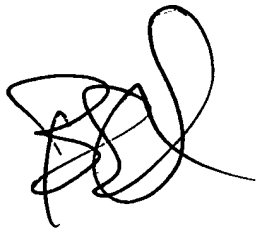
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER